UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 7, 2005

MEMORANDUM

Subject: Efficacy Review for Sterilex Ultra Disinfectant Cleaner Solution 1, EPA File Symbol: 63761-I
DP Barcode: D315610

From: Michele E. Wingfield, Chief
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Applicant: The Sterilex Corporation
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Formulation From Label:

Active Ingredient(s)	% by wt
n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chloride	3.00
n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chloride	3.00

(1) BACKGROUND

This submission is for registration of the product as a one-step hospital disinfectant, for use in healthcare facilities, federally inspected food processing facilities and meat and poultry plants, farm premises and other institutional settings. The submitted study, MRID No. 456047-

6, was conducted at ViroMed Laboratories, which is located at 6101 Blue Circle Drive, Minneapolis, MN 55343. The study was completed on August 27, 1998. Andrew T. Snyder is listed as the Study Director.

The test substance used in this study is Ultra-Kleen Solution 1. This product is substantially similar to the proposed product, Ultra Disinfectant Cleaner Solution 1.

MRID Nos. 460335-02,03, and 04, have been previously reviewed and approved. These studies were submitted to support the confirmatory efficacy of Ultra Disinfectant Cleaner Solution 1 and to add the microorganisms *Escherichia coli* 0157:H7 and *Listeria monocytogenes*. These three studies were conducted in the presence of 400 ppm hard water and a 5% organic soil load.

(2) USE DIRECTIONS

Sterilex Ultra Disinfectant Cleaner Solution 1 is one part of a two-part product. It must be used in conjunction with Sterilex Ultra Activator Solution. When mixed with the activator, this product is a one-step, hospital disinfectant at a dilution of 12 fl. oz. per gallon. Bactericidal according to the current AOAC Use-Dilution Test Method modified in the presence of 400 ppm hard water plus 5% organic serum.

Add 12.8 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 fl. oz. of Sterilex Ultra Activator Solution to 1 gal. tap water in an appropriate plastic container and stir. Thoroughly wet surfaces with the use solution by poring, wiping, brushing, scrubbing, spraying with a course trigger sprayer, sponging, using a clean in place system, pumping it through the system, drawing it through the system or mopping. Allow the surfaces to remain wet for at least 10 minutes. Rinse all surfaces thoroughly with a potable water rinse.

(3) AGENCY STANDARD FOR HOSPITAL DISINFECTANT CLAIM

Disinfectants (hospital or medical environment efficacy). When a product is recommended in labeling for use in hospitals, clinics, dental offices, nursing homes, sickrooms, or any other medical-related facility, the following requirements apply.

(1) **Test standard**. Sixty carriers for each of three samples, representing three different batches, one of which is at least 60 days old, must be tested against each of the following: *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442).

(2) **Performance standard**. The product must kill the test microorganisms on 59 out of each set of 60 carriers/slides to provide significance at the 95 percent confidence level.

Supplemental Claims

An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

(4) COMMENTS ON THE SUBMITTED EFFICACY STUDY

1. MRID 456047-06 "AOAC Use Dilution Method" for Ultra Kleen Solution 1 and Ultra Kleen Solution 2BHW, by Andrew T. Snyder. Study conducted at ViroMed Laboratories, Inc. Study completion date – August 27, 1998.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Salmonella choleraesuis* (ATCC 10708), and, *Pseudomonas aeruginosa* (ATCC 15442). Three lots of the product (lot nos. 7H085, 7J027 & 7K070) and three lots of the activator (lot nos. 8B007, 8B055, & 8C079) were tested using the AOAC Use Dilution Method. The use solution was made by adding 100 ml of product and 100 ml of activator to 800 ml of 400 ppm AOAC synthetic hard water (a 1:5 dilution). **No organic soil load was added to the test system.** Sixty carriers were tested against each organism against each batch/activator combination. The testing was conducted for a ten minute contact time at room temperature (20°C). Letheen broth was used as the neutralizer and subculture medium. Controls included: neutralization confirmation, phenol resistance, and viability controls. All controls were reported to be within specifications.

(5) RESULTS

Lot Number	Organism	Carrier Counts	Number +/ Number Tested
7H085 + 8B007	*Staphylococcus aureus*	5.7×10^6 cfu/carrier	0/60
	Salmonella choleraesuis	3.2×10^6 cfu/carrier	0/60
	Pseudomonas aeruginosa	5.3×10^5 cfu/carrier	1/60
7J027 + 8B055	*Staphylococcus aureus*	5.7×10^6 cfu/carrier	0/60
	Salmonella choleraesuis	3.2×10^6 cfu/carrier	0/60
	Pseudomonas aeruginosa	5.3×10^5 cfu/carrier	1/60
7K070 + 8C079	*Staphylococcus aureus*	5.7×10^6 cfu/carrier	0/60
	Salmonella choleraesuis	3.2×10^5 cfu/carrier	0/60
	Pseudomonas aeruginosa	5.3×10^5 cfu/carrier	0/60

(6) CONCLUSIONS

When diluted 1:5 in 400 ppm hard water and tested at a contact time of 10 minutes at room temperature, Ultra-Kleen Solution 1 appears to be effective against *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). The data supports the use of this product as a hospital disinfectant.

(7) RECOMMENDATIONS

1. MRID Nos. 456047-6 and 460335-02 support the use of the product as a hospital disinfectant when tested at a dilution of 12.8 fl. oz. of product and 12.8 fl. oz. of activator in 1 gallon of 400 ppm hard water, at a contact time of ten minutes at room temperature (20°C).

2. MRID Nos. 460335-03 & 04 support the use of the product as a hospital disinfectant, under the same conditions listed above, against the additional microorganisms *Escherichia coli* 0157:H7 and *Listeria monocytogenes*. These three studies were conducted in the presence of 400 ppm hard water and a 5% organic soil load.

3. Although the basic data, MRID 456047-06 was not conducted in the presence of organic soil, the Agency will allow the one-step disinfection claim because the confirmatory study and the additional microorganism studies were successfully conducted with a 5% soil load.

(8) LABELING COMMENTS

1. Under the heading "Directions for Use" in the third paragraph, revise "12 fl. oz. per gallon" to read, "12.8 fl. oz. of each component per gallon". Within that same paragraph, revise "hospital-use disinfectant" to read, "hospital disinfectant".

2. Add the American Type Culture Collection (ATCC) numbers to each of the organisms listed on page 2 of 10.

3. Revise the statement "hard, nonporous surfaces" to read, "hard, nonporous, inanimate, environmental surfaces" everywhere it appears on the label.

4. On page 3 of 10, in the first paragraph, revise the statement, "medical devices and equipment" to read, "non-critical medical devices and equipment surfaces". In addition, add "or mucous membranes" to the list of restricted body sites in parenthesis.

5. It is unlikely that the solution will remain in contact for the required 10 minutes with the surfaces in water reservoir tubing, water reservoir pipes and piping systems, therefore, these sites (found on page 3 of 10) must be removed from the label.

6. The following sites (found on page 3 of 10) must be removed from the label because they are considered food contact surfaces and require the use of a food contact surface sanitizer: plastic and other non-porous cutting boards and chopping blocks; refrigerator bins for meat, fruit, and vegetables; injectors; knives; slicers; deboners; saws; grinders; cutters; dairy equipment; beer fermentation and holding tanks; brewery pasteurizers, wine fermentation tanks; beverage dispensing machines; beverage transfer lines; bottling or premix dispensing equipment; drinking water coolers; ice making machines; transfer line tubing; water lines; watering storage and display equipment; tables; and highchairs.

7. Remove all references for use in clean in place systems and transfer lines everywhere they appear on the label. These sites are for food contact surface

sanitization, not disinfection.

8. Under the heading "Instrument Pre-Soak", at the end of the paragraph, add the sentence, "Instruments must undergo high-level disinfection or sterilization following pre-soak treatment."

9. This product is not approved for use as a food contact surface sanitizer, therefore, the directions for use as a disinfectant of food processing equipment are not acceptable and must be removed from the label. This also applies to the directions for use in breweries, wineries and other beverage manufacturing facilities and the directions for use in restaurants and other food preparation areas. This product may only be used on floors, walls and other non-food contact environmental surfaces in these areas.

END